PCT

WORLD INTELLECTUAL PROPERTY ORGANIZA'IION International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ :		(11) International Publication Number:	WO 98/17187
A61B 17/36, 8/00	A1	(43) International Publication Date:	30 April 1998 (30.04.98)

(21) International Application Number: PCT/US97/19552

(22) International Filing Date: 22 October 1997 (22.10.97)

(30) Priority Data:

08/735,036 22 October 1996 (22.10.96) US Not furnished 15 October 1997 (15.10.97) US

(71) Applicant: HEARTPORT, INC. [US/US]; 200 Chesapeake Drive, Redwood City, CA 94063 (US).

(72) Inventors: COX, James, L.; 7 Dromera Road, St. Louis, MO 63124 (US). BOYD, Stephen, W.; 333 Palomar Drive, Redwood City, CA 94062 (US). GIFFORD, Hanson, S., III; 3180 Woodside Road, Woodside, CA 94062 (US). VASKA, Matthias; 13944 Fremont Pines Lane, Los Altos, CA 94002 (US). MERRICK, Daniel, D.; 168 La Sonoma Way, Alamo, CA 94507 (US).

(74) Agent: HESLIN, James, M.; Townsend and Townsend and Crew LLP, Two Embarcadero Center, 8th floor, San Francisco, CA 94111-3834 (US).

(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT. SE).

Published

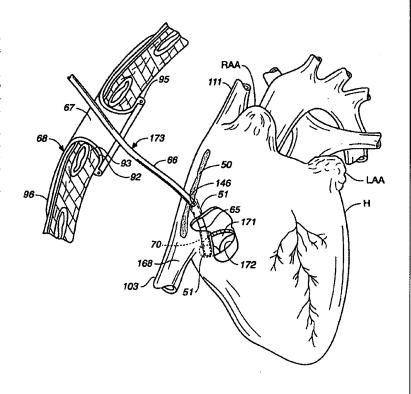
With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: SURGICAL SYSTEM AND PROCEDURE FOR TREATMENT OF MEDICALLY REFRACTORY ATRIAL FIBRILLATION

(57) Abstract

The invention provides surgical systems and methods for ablating heart tissue within the interior and/or exterior of the heart. A plurality of probes (57) is provided with each probe configured for introduction into the chest for engaging the heart. Each probe includes an elongated shaft (66) having an elongated ablating surface (65) of a predetermined shape. The elongated shaft (66) and the elongated ablating surface (65) of each probe (57) are configured to ablate a portion of the heart. A sealing device (145) affixed to the heart tissue forms a hemostatic seal between the probe and the penetration in the heart to inhibit blood loss therethrough.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Amenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Laixembourg	SN	Senegal
ΑU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
ΛZ	Azerbaijan	GB	United Kingdom	MC	Мопасо	TD	Chad
BA	Bosnia and Herzegovina	GB	Georgia	MD	Republic of Moklova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	ТJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav	TM	Turkmenistan
BF	Burkina Faso	GR	Greece		Republic of Macedonia	TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
ВJ	Bonin	1E	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	11.	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's	NZ	New Zealand		
CM	Cameroon		Republic of Korea	PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cub ₂	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

1

SURGICAL SYSTEM AND PROCEDURE FOR TREATMENT OF MEDICALLY REFRACTORY ATRIAL FIBRILLATION

5

10

15

20

25

30

35

BACKGROUND OF THE INVENTION

It is well documented that atrial fibrillation, either alone or as a consequence of other cardiac disease, continues to persist as the most common cardiac arrhythmia. According to recent estimates, more than one million people in the U.S. suffer from this common arrhythmia, roughly 0.15% to 1.0% of the population. Moreover, the prevalence of this cardiac disease increases with age, affecting nearly 8% to 17% of those over 60 years of age.

Although atrial fibrillation may occur alone, this arrhythmia often associates with numerous cardiovascular conditions, including congestive heart failure, hypertensive cardiovascular disease, myocardial infarcation, rheumatic heart disease and stroke. Regardless, three separate detrimental sequelae result: (1) a change in the ventricular response, including the onset of an irregular ventricular rhythm and an increase in ventricular rate; (2) detrimental hemodynamic consequences resulting from loss of atroventricular synchrony, decreased ventricular filling time, and possible atrioventricular valve regurgitation; and (3) an increased likelihood of sustaining a thromboembolic event because of loss of effective contraction and atrial stasis of blood in the left atrium.

Atrial arrythmia may be treated using several methods. Pharmacological treatment of atrial fibrillation, for example, is initially the preferred approach, first to maintain normal sinus rhythm, or secondly to decrease the ventricular response rate. While these medications may reduce the risk of thrombus collecting in the atrial appendages if the atrial fibrillation can be converted to sinus rhythm, this form of treatment is not always effective. Patients with

WO 98/17187 PCT/US97/19552

2

continued atrial fibrillation and only ventricular rate control continue to suffer from irregular heartbeats and from the effects of impaired hemodynamics due to the lack of normal sequential atrioventricular contractions, as well as continue to face a significant risk of thromboembolism.

5

10

15

20

25

30

35

Other forms of treatment include chemical cardioversion to normal sinus rhythm, electrical cardioversion, and RF catheter ablation of selected areas determined by mapping. In the more recent past, other surgical procedures have been developed for atrial fibrillation, including left atrial isolation, transvenous catheter or cryosurgical ablation of His bundle, and the Corridor procedure, which have effectively eliminated irregular ventricular rhythm. However, these procedures have for the most part failed to restore normal cardiac hemodynamics, or alleviate the patient's vulnerability to thromboembolism because the atria are allowed to continue to fibrillate. Accordingly, a more effective surgical treatment was required to cure medically refractory atrial fibrillation of the heart.

On the basis of electrophysiologic mapping of the atria and identification of macroreentrant circuits, a surgical approach was developed which effectively creates an electrical maze in the atrium (i.e., the MAZE procedure) and precludes the ability of the atria to fibrillate. Briefly, in the procedure commonly referred to as the MAZE III procedure, strategic atrial incisions are performed to prevent atrial reentry and allow sinus impulses to activate the entire atrial myocardium, thereby preserving atrial transport function postoperatively. Since atrial fibrillation is characterized by the presence of multiple macroreentrant circuits that are fleeting in nature and can occur anywhere in the atria, it is prudent to interrupt all of the potential pathways for atrial macroreentrant circuits. These circuits, incidentally, have been identified by intraoperative mapping both experimentally and clinically in patients.

Generally, this procedure includes the excision of both atrial appendages, and the electrical isolation of the